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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/09/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/986,116

Applicant(s)

Berkulin et al.

Examiner

Christopher Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 31, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-15 is/are pending in the application.
- 4a) Of the above, claim(s) 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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DETAILED ACTION

Applicant's election of Group I, claims 8-12, in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8-12 are presented for examination on the merits.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is rendered vague and indefinite for the following reasons:

- the phrase "process for preparing dry extracts from a liquid extract" (line 1) is unclear because the plural recitation "dry extracts" therein - e.g., how many dry extracts are prepared from the singular liquid extract and how are they different from one another? It is suggested that the phrase "dry extracts" be replaced with --a dry extract--.
- the phrase "characterized in that" (line 2) is ambiguous and, therefore, any limitations recited thereafter are unclear.

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- the metes and bounds of the phrase "at least one additional substance" (recited twice) are not clearly nor adequately delineated - e.g., such a substance could read upon dry air used within the spray-drying process as well as an actual dry agent from among those disclosed. It is clear from the instant specification that the additional substance (i.e., auxiliary agent - please note that the disclosed auxiliary agents are generally considered binders in the pharmaceutical art, not galenic auxiliary agents as discussed below) is an essential element of the disclosed/demonstrated invention. As such, it should be clearly defined in the claim language itself (see, e.g., MPEP 2172.01). It is suggested that this essential ingredient be recited in Markush language - e.g., --at least one auxiliary agent selected from the group consisting of ... (those recited in claim 11).

- the phrase "said at least one additional substance is added to the spray-drying process in a dry form during the spray-drying process" (lines 2-4) is exceedingly vague and indefinite because the overall phrase is grammatically awkward and confusing, and it fails to adequately delineate the metes and bounds of this essential step - e.g., this phrase reads upon mixing the liquid extract with a dry auxiliary agent such as those recited in claim 11 to form a spray drying solution which is then spray-dried since this overall spray-drying process includes mixing and spray-drying a liquid extract solution. In other words, it is unclear as to the metes and bounds of "the spray-drying process" because it is unclear if this is meant to read only upon the spray-drying step itself or the overall process involved with spray-drying which is recognized in the art to often include mixing such dry auxiliary agents with liquid extracts to form spray-dried products which are then spray-dried, including many herbal products.

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In claim 10, the term "galenic" is unclear with respect to the auxiliary agents instantly disclosed - i.e., the term "galenic" means "pertaining to the ancient system of medicine taught and practiced by Galenus, or Galen" (Dorland's Medical Dictionary, 27th ed., 1988). Thus, this term does not appear to be properly definitive of the various auxiliary agents instantly disclosed and claimed. It is suggested that this term be omitted from the claim language.

Claim 11 is rendered vague and indefinite by the trademark term "Povidone®", at line 3. The relationship between a trademark and the product it identifies is indefinite, uncertain, and arbitrary. The formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark. In patent specifications, especially in the claim language, every element or ingredient of the product should be set forth in positive, exact, intelligible language, so that there will be no uncertainty as to what is meant. Arbitrary trademarks which are liable to mean different things at the pleasure of manufacturers do not constitute such language. *Ex Parte Kattwinkle*, 12 USPQ 11 (Bd. App. 1931).

Claim 11 recites the limitation "the particle size" in line 1. There is insufficient antecedent basis for this limitation in the claim because claim 11 depends from claim 8 and the auxiliary substance recited in claim 8 is not defined as being in particulate form (e.g., the auxiliary substance of claim 8 could simply be dry air, or other non-particulate dry substance).

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

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Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Schumacher et al. (US 4,519,961), with evidence provided by Diaz et al. (US 5,891,441) and Chevance (EP 419308 - DWPI Abstract).

A process for preparing dry extracts from liquid extract and at least one additional substance via adding the one additional substance in dry form during the spray drying process is claimed.

Schumacher et al. teaches a spray-drying process for preparing dry extract powders from liquid extracts via the addition of one or more auxiliary dry agents, such as silica, calcium stearate, and/or magnesium stearate, directly during the step of spray-drying. Schumacher et al. further disclose that the liquid extract can be prepared from plant material - i.e., pectin (which is

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defined by Webster's Dictionary [1988] as any group of complex colloidal substances found in ripe fruits such as apples) and gum arabic (which is defined by Webster's Dictionary [1988] as a gum extracted from an African tree of the genus *Acacia*)* - see entire document including Abstract, Figures, col 1, lines 6-35; col 2, lines 13-41; col 3, lines 3-38, and Examples)

Therefore, the reference is deemed to anticipate the instant claims above.

* Please note, as evidenced by Diaz et al. and Chevance (to name a few), it is notoriously well known in the herbal art that pectin and gum arabic, respectively, constitute medicinal plant extracts as both have art-recognized therapeutic medicinal activity (see, e.g., abstracts of these two references).

Claims 8, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Tritsch et al. (US 6,030,645) or by Hohl et al. (US 4,395,491).

Tritsch teaches a spray-drying process for preparing dry particles from various types of oleophilic liquid extract solutions via the addition of one or more auxiliary dry agents, such as calcium silicate, microcrystalline cellulose, magnesium silicate, calcium stearate, and/or magnesium stearate, directly during the step of spray-drying (see entire document including col 2, lines 14-45, col 3, lines 20-30, and Examples).

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Hohl et al. teaches a spray-drying process for preparing dry particles from a microbial liquid extract fluid via the addition of one or more auxiliary dry agents, such as calcium carbonate, silicic acid, chalk, diatomaceous earth, talk, and/or kieselguhr, directly during the step of spray-drying.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Menon et al. (US 6,447,815).

Menon teaches a spray-drying process of preparing dry herbal powders from liquid herbal extracts, including medicinal herbal plants, via the addition of an auxiliary dry agent, such as maltodextrin during the process of spray-drying (see, e.g., Figure 3; col 4, lines 54-60; col 5, lines 23-32).

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schumacher et al. (US 4,519,961), with evidence provided by Diaz et al. (US 5,891,441) and Chevance (EP 419308 - DWPI Abstract).

Schumacher et al. teaches a spray-drying process for preparing dry extract powders from liquid extracts via the addition of one or more auxiliary dry agents, such as silica, calcium stearate, and/or magnesium stearate, directly during the step of spray-drying. Schumacher et al. further disclose that the liquid extract can be prepared from plant material - i.e., pectin (which is defined by Webster's Dictionary [1988] as any group of complex colloidal substances found in ripe fruits such as apples) and gum arabic (which is defined by Webster's Dictionary [1988] as a gum extracted from an African tree of the genus *Acacia*)^{*} - see entire document including Abstract, Figures, col 1, lines 6-35; col 2, lines 13-41; col 3, lines 3-38, and Examples).

Schumacher et al. do not expressly teach the auxiliary agents having a particle size within the broad micrometer range instantly claimed. However, this size range would appear to be intrinsic to such binder particles. Nevertheless, Schumacher et al. disclose that the particle size of the final product should have a size of 100-600 μm . Accordingly, the result-effective adjustment in the particle size of the auxiliary agent so as to achieve a final product particle size within the range disclosed by Schumacher et al. is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

* Please note, as evidenced by Diaz et al. and Chevance (to name a few), it is notoriously well known in the herbal art that pectin and gum arabic, respectively, constitute medicinal plant extracts as both have art-recognized therapeutic medicinal activity (see, e.g., abstracts of these two references).

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.



Christopher R. Tate
Primary Examiner, Group 1654